IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC., Plaintiff, vs. DEY, L.P. and DEY, INC., Defendants.	C.A. No. 06-113-JJF CONSOLIDATED **PUBLIC VERSION**
SEPRACOR INC., Plaintiff, vs. BARR LABORATORIES, INC., Defendant.	

BARR'S OPENING MEMORANDUM REGARDING CLAIM CONSTRUCTION

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INTRODUCTION

Sepracor asserts that Barr infringes five patents. All five are related patents, continuations of one another in the same family tree, and all share the same patent specification. The patents generally relate to the use of a drug known as R-albuterol to treat asthma. The prior art disclosed albuterol, a drug that included both R-albuterol and S-albuterol as a treatment for asthma, and identified R-albuterol as the active component of albuterol. To obtain the patents, Sepracor distinguished the prior art by arguing that the drug component R-albuterol, administered without the inactive S-albuterol component, reduced "side effects." Four of the five patents contain the "side effects" or "adverse effects" claim limitation. "Side effects" (or "adverse effects") as used in U.S. Patents 5,362,755; 5,547,994; 5,760,090; and 5,884,002 is the claim term that Barr asks the Court to construe.

The specification common to these patents defined "side effects" as "central nervous system stimulatory effects and cardiac arrhythmia" and "teratogenic effects." (Ex. 1, '755 Patent, col. 3, lines 28-31, 33-35.) No other side effects were disclosed. Sepracor now seeks to expand the term "side effects" to include unspecified effects and effects that it did not know when it filed its patent application. Sepracor's construction would render the side effects term invalid not only as indefinite (for failure to provide a clearly defined boundary of which side effects are covered) but also as lacking written description (for failure of the specification to demonstrate that the inventors had possession of the claimed invention). Barr therefore asks the Court to construe "side effects" to mean the central nervous system, cardiac, and teratogenic effects set forth in the patent specification.

I. FACTUAL BACKGROUND

A. Some Chemistry Regarding Albuterol

The patents in suit generally relate to the use of "R-albuterol" to treat asthma. Albuterol (sold under the "Ventolin®" brand name) was developed in the 1960s to treat asthma. (Ex. 6, Jenny Bryan, *Ventolin Remains a Breath of Fresh Air for Asthma Sufferers, after 40 Years*, 279 The Pharm. J. 404, 404 (October 13, 2007), *available at* http://www.pjonline.com.) Albuterol is a chiral compound, meaning that it naturally exists as a mixture of two "mirror image" molecules. These "mirror image" molecules are known as isomers.[1] Commonly, "R-albuterol" is used to refer to the R isomer, "S-albuterol" is used to refer to the S isomer, and "RS-albuterol" or "racemic albuterol" is used to refer to the combined mixture (naturally containing half "R" isomer and half "S" isomer).

B. The State Of The Art As Shown By The Prior Art

During prosecution of the patents in suit, the Patent Office pointed out that the prior art, dating back to the early 1970's, already showed that albuterol, the racemic mixture of R and S, can be used to treat asthma, already showed that albuterol is a chiral compound, and already showed that R-albuterol is the isomer effective for treating asthma. (Ex. 8, 3/22/91 Office Action, at 2; Ex. 9, 12/9/91 Office Action, at 3.) So by January 5, 1990, when Sepracor first applied for its patents, prior art references disclosed the use of R-albuterol to treat asthma. During patent prosecution, Sepracor distinguished these references, arguing that they did not expressly disclose that the use of R-albuterol instead of racemic albuterol reduced side effects. (*See, e.g.,* Ex. 10, Sepracor's 7/14/92 Amendment, at 2-4.; Ex. 11, Sepracor's 2/10/93

[1] A common analogy is to refer to a person's two hands, where the right hand and left hand have the same parts, but are mirror images. For albuterol, the two chemical "hands" are given the labels "R" and "S".

Amendment, at 4-5; Ex. 13, Sepracor's 7/23/93 Amendment, at. 3-4; Ex. 14, Sepracor's 12/7/93 Preliminary Remarks, at 5-9, 12.)

C. Sepracor's "Side Effects" Limitation To Distinguish Prior Art

Sepracor's originally-filed patent claims did not list side effects as a limitation. (Ex. 7, Sepracor's 1/5/90 Application, at 8-9.) During prosecution, Sepracor amended its pending claims to add this language, so it could argue that the claims were patentable over the prior art. Sepracor first amended the claims to add the limitation "while simultaneously reducing undesirable side effects" during prosecution of the '755 patent, the first in the series of patents in suit. (Ex. 10, Sepracor's 7/14/92 Amendment, at 1-2.) When it made this amendment, Sepracor argued that "[t]he [prior art] references do not indicate that undesirable side effects can be minimized by administering one of the isomers." (*Id.* at 4.)

In fact, Sepracor's only argument to distinguish the prior art was that R-albuterol allegedly reduced certain side effects:

- "undesirable side effects are associated with the therapeutically inactive isomer, *i.e.* the S(+) isomer, of albuterol, but not with the R(-) isomer. Applicants have, therefore, made the unexpected disclosure that the claimed isomer does not have the same type of activity as the racemic mixture." (*Id.* at 3 (emphasis in original)).
- "The thrust of Applicant's invention is the treatment of asthma while reducing side effects associated with administration of racemic albuterol." (Ex. 11, Sepracor's 2/10/93 Amendment, at 3.)
- "Applicants disclose an unexpected diminution in side effects when the pure R isomer is administered." (*Id.* at 5.)
- "The thrust of applicants' invention is the reduction of side effects, which arise in the treatment of asthma with racemic albuterol, by the administration of the R-(-) albuterol in place of racemic albuterol." (Ex. 13, Sepracor's 7/23/93 Preliminary Remarks, at 2-3.)
- "Applicants' invention is directed to a method of treating asthma and reducing the undesirable side effects associated with racemic albuterol by using the R isomer of albuterol substantially free of the S isomer." (Ex. 14, Sepracor's 12/7/93 Preliminary Remarks, at 2.)

- "Indeed, the unexpected diminution in side effects when the pure R isomer of albuterol is administered is the basis of the instant application, but it is not suggested by any of the references." (*Id.* at 8.)

According to Sepracor, "[t]he references do not indicate that undesirable side effects can be minimized by administering one of the isomers." (Ex. 10, Sepracor's 7/14/92 Amendment, at 4.) Sepracor noted that its patent disclosure was new because "in January 1990 when the grandparent of the present application was filed, there was no teaching in the art that the use of pure R-albuterol enjoyed any advantage in diminution of side effects." (Ex. 14, Sepracor's 12/7/93 Preliminary Remarks, at 9.)

Sepracor relied on its original patent specification, filed in January 1990, to provide support for its "reduced side effects" claim limitation. (Ex. 10, Sepracor's 7/14/92 Amendment, at 2.) Throughout the two-page specification, Sepracor specifically reported that using R-albuterol would reduce the "**central nervous system**," "**cardiac**" and "**teratogenic**" side effects:

- "central nervous system stimulatory effects and cardiac arrhythmia" (Ex. 1, '755 Patent, col. 1, lines 47-59.)
- "tremor, nervousness, shakiness, dizziness and increased appetite, and particularly, cardiac arrhythmia" (Ex. 1, '755 Patent, col. 1, lines 56-61.)
- "central nervous system stimulatory effects and cardiac disorders" (Ex. 1, '755 Patent, col. 2, lines 4-9.)
- "reduces the teratogenic potential" (Ex. 1, '755 Patent, col. 1, lines 66-68.)

The specification concluded by again referring to **central nervous system, cardiac, and teratogenic** side effects, this time providing additional examples of these types of side effects:

> The present composition and method provide an effective treatment for asthma while minimizing the undesirable side effects associated with albuterol use. These side effects include central nervous system effects, such as tremor, nervousness, shakiness, dizziness and increased appetite, and cardiac effects, such as cardiac arrhythmia. (*Id.* at col. 3, lines 25-31.)

> In addition, teratogenic effects associated with albuterol are believed to reside in the S(+) enantiomer. Thus, administering the pure R(-) isomer may reduce the teratogenic potential associated with albuterol. (*Id.* at col. 3, lines 33-37.)

These were the only side effects Sepracor disclosed. These provided the basis for Sepracor's claim amendment and argument that using the R-isomer alone reduced side effects.

Sepracor relied upon the same "side effects" argument during prosecution of the other asserted patents. For the second issued patent, U.S. Patent No. 5,547,994, Sepracor argued that "[t]he unexpected diminution in side effects when the pure isomer of albuterol is administered is the basis of the instant application, and is not suggested in any of the references." (Ex. 15, Sepracor's 6/9/95 Amendment, at 7.) For the remaining three asserted patents -- U.S. Patents No. 5,760,090; 5,884,002; and 6,083,993 -- Sepracor relied only on the same arguments "of record" to obtain allowance of the asserted patents. (Ex. 17, Sepracor's 5/7/97 Amendment, at 5-6; Ex. 19, Sepracor's 4/21/98 Amendment, at 4; Ex. 20, Sepracor's 12/17/99 Amendment, at 5.) No new arguments were made other than to the "side effects" claim limitation in order to distinguish the prior art.

The patents issued based on Sepracor's argued distinction over the prior art using the "side effects" limitation. A representative resulting claim is claim 1 of the '755 patent:

> 1. A method of treating asthma in an individual with albuterol, ***while reducing side effects*** associated with chronic administration of racemic albuterol, comprising
>
> chronically administering to the individual a quantity of an optically pure R(-) isomer of albuterol sufficient to result in bronchodilation
>
> ***while simultaneously reducing undesirable side effects***,
>
> said R isomer being substantially free of its S(+) isomer.

Later in the case, Barr will show that the patent does not demonstrate any reduction in side effects, a failure that renders the patent invalid for several reasons and means that Barr does not infringe. But for purposes of claim construction, the issue presented is which side effects are covered by the claim. Barr proposes that the side effects supported by the patent specification are "central nervous system stimulatory effects, "cardiac disorders," and "teratogenic effects" as set forth in the specification. There is no support for any other side effects, and allowing others would violate the definiteness and written description requirements of 35 U.S.C. § 112.

II. LEGAL BACKGROUND

A. Claim Construction

Claim construction is a pure question of law. *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 970-71, 978 (Fed. Cir. 1995) (*en banc*); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998) (*en banc*). In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), the Federal Circuit stressed the importance of intrinsic evidence -- the claim language, the specification, and the prosecution history -- when construing claim terms. *Id.* at 1317; *see also Nice Sys. v. Witness Sys.*, 528 F. Supp.2d 470, 474 (D. Del. 2007). "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313; *see also Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005). Under *Phillips* and its progeny, the patentee "is not entitled to a claim construction divorced from the context of the written description and prosecution history." *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1144-45 (Fed. Cir. 2005).

Since a patent's "claims are directed to the invention that is described in the specification," the specification drives the claim construction analysis. *Phillips*, 415 F.3d at 1316 (quoting *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001)). The

specification tends to be "dispositive" because "it is the single best guide to the meaning of a disputed term." *Nice Sys.*, 528 F. Supp.2d at 474 (quoting *Phillips*, 415 F.3d at 1315). Since "[t]he patent system is based on the proposition that claims cover only the invented subject matter," *Phillips*, 415 F.3d at 1321, the specification is meant "to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." *Id.* at 1323 (citing *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987)). Therefore, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317. After all, "the scope and outer boundary of claims is set by the patentee's description of his invention," and "the claims cannot be of broader scope than the invention that is set forth in the specification." *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1337-38, 1340 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1313-14). Moreover, "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313 (internal citations omitted).

Although this is the claim construction phase of the case, it is an axiom of claim construction that "claims are best construed to preserve their validity," where possible. *E.g., Medtronic Navigation, Inc. v. BrainLab Medizinische Computersysteme GmbH*, 222 F. App'x 952, 956 (Fed. Cir. 2007) (internal citations omitted). The Court should therefore consider issues of indefiniteness and written description in the context of claim construction. As shown below, Sepracor's proposed construction would render the claims invalid as indefinite and for failing to satisfy the written description requirement and should therefore be rejected.

B. Indefiniteness

A patent applicant is required through its claims to "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. A claim term is indefinite, and thus invalid, "if the claim is insolubly ambiguous, and no narrowing construction can properly be adopted." *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338-39 (Fed. Cir. 2003) (internal citations omitted). The statutory requirement of particularity and distinctness in claims is met "only when they clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise." *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942). A patent claim meets the definiteness requirement only when a person of skill in the art can "discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as [his or] her knowledge of the relevant art area." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008).

Therefore, the claims must provide sufficient "guidance as to what one of ordinary skill in the art would interpret the claim to require." *Honeywell*, 341 F.3d at 1340. Even if it is possible to reduce a claim term's definition to words, it is "still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Halliburton*, 514 F.3d at 1251. For example, even though words can be used to describe the claim, the scope of the claim is indefinite if it depends "solely on the unrestrained, subjective opinion of a particular individual purportedly practicing the invention." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) (internal citation omitted). This requirement is all the more significant for those claim terms that are used to distinguish the claimed invention from the prior art. *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991).

C. Written Description

The written description requirement is also found in 35 U.S.C. § 112: "The specification shall contain a written description of the invention...." To satisfy this requirement, the patent specification "must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, i.e., that the patentee invented what is claimed." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005) (additional citations omitted). In *LizardTech*, the specification provided "only a single way of creating" a particular waveform. *Id.* at 1344. Because the specification did not provide more generic support for other ways of creating the waveform, other techniques not disclosed in the specification were excluded from the scope of the claims. *Id.* at 1344-45. Claims are not valid if they do not find written support in the specification. *See In re Curtis*, 354 F.3d 1347, 1354-55 (Fed. Cir. 2004) (finding one type of material described in specification insufficient to describe broad category of related materials).

ARGUMENT

As shown above, throughout the prosecution of the patents in suit, Sepracor's one and only distinction over the prior art was the "reducing side effects" claim limitation.[2] Special scrutiny is therefore required for this claim term, because it is ***the*** term that Sepracor used to distinguish the prior art. *See Halliburton*, 514 F.3d at 1252-53 (noting the importance of prior art differentiation to the definiteness inquiry); *see also Amgen*, 927 F.2d at 1218 (heightening invalidity standard in view of close prior art). Indeed, as Sepracor argued, "[t]he thrust of

[2] Barr does not admit that is any side effect reduction, nor that there is anything novel about Sepracor's claims. For purposes of claim construction, the issue is the meaning of the terms, determined in light of the intrinsic evidence.

applicants' invention is the treatment of asthma while reducing the side effects associated with the administration of racemic albuterol." (Ex. 11, Sepracor's 2/10/93 Amendment, at 4.)

Below is a table listing the claim terms as found in each patent, and Barr's and Sepracor's proposals for these terms. Barr reserves the right to amend or add to the list of disputed terms depending on the proposed claim terms and arguments submitted by Sepracor and Dey.

Claim Term	**Barr's Construction**	**Sepracor's Construction**
'755 patent: "side effects associated with chronic administration of racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." *See* '755 Patent, col. 3, lines 28-31, 33-35.	The side effects are those associated with chronic administration of racemic albuterol
'994 patent: "side effects associated with the acute administration of racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." *See* '755 Patent, col. 3, lines 28-31, 33-35.	The side effects are those associated with acute administration of racemic albuterol
'090 patent: "while reducing side effects associated with the administration of racemic albuterol" '002 patent: "while reducing the concomitant liability of adverse effects associated with racemic albuterol"	"Central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects associated with chronic administration of racemic albuterol." *See* '755 Patent, col. 3, lines 28-31, 33-35.	The adverse effects or side effects are those associated with the administration of racemic albuterol

III. "SIDE EFFECTS" SHOULD MEAN THOSE SIDE EFFECTS DISCLOSED IN THE SPECIFICATION

As shown in the above table, the term "side effects" (or "adverse effects") is found in four of the five asserted patents (the '755, '994, '090, and '002 patents). The claim language refers variously to "side effects" associated with "chronic administration," "acute administration," or "administration" of racemic albuterol. The specification does not distinguish between different classes of side effects, such as those associated with chronic administration versus those associated with acute administration, but instead identifies specific side effects Sepracor asserted would be covered by the asserted claims. "Side effects" therefore should be construed in the same way throughout the claims.

The specification defines "side effects" as related to the central nervous system, the heart, and teratogenic effects. In the specification, Sepracor expressly stated that: "These side effects include **central nervous system effects**, such as tremor, nervousness, shakiness, dizziness and increased appetite, and **cardiac effects**, such as cardiac arrhythmia," and could include "**teratogenic effects** associated with albuterol." (Ex. 1, '755 Patent, col. 3, lines 25-35.) These same categories of central nervous system, cardiac, and teratogenic side effects were repeated throughout the two-page patent specification, as shown above.[3]

In January 1990, when Sepracor filed for its patents, it was only aware of, and exclusively disclosed, central nervous system effects, cardiac effects, and teratogenic effects.

REDACTED

Thus, quoting from column 3, lines 28-35 of the patent specification, the term "side effects" should mean "central nervous

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[3] **REDACTED**

system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite) and cardiac effects (such as cardiac arrhythmia)" and "in addition, teratogenic effects associated with albuterol." (Ex. 1, '755 Patent, col. 3, lines 25-35.) Barr's construction thus adopts the definition used by Sepracor when defining its invention in its original patent specification that came with its January 1990 application.

IV. SEPRACOR'S PROPOSED CONSTRUCTION WOULD MAKE THE CLAIMS INVALID

Notwithstanding the specification, Sepracor asks the Court to leave open the possible list of side effects, and construe "side effects" to mean "those associated with" racemic albuterol, without identifying what those side effects are. Sepracor did not know of, nor describe, any side effects other than those listed in its patent. Therefore, to the extent that it covers anything beyond the side effects specifically set forth in the specification, there is no support for Sepracor's overbroad reference to "those [side effects] associated with" racemic albuterol. Sepracor's proposed construction will render the claims (1) invalid as indefinite and (2) invalid because of the written description requirement. Because the specification defines the term and the claims are to be construed to avoid invalidity, Sepracor's proposed construction should be rejected.

A. Sepracor's Proposal Will Render The Claims Indefinite

Sepracor's proposed construction provides no list and no guidance as to what "side effects" are included within the scope of the asserted claims. "The Supreme Court has stated that '[t]he statutory requirement of particularity and distinctness in claims is met only when [the claims] clearly distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise." *Halliburton*, 514 F.3d at 1249 (quoting *United Carbon*, 317 U.S. at 236). Without defining which side effects are reduced, Sepracor

provides no basis to determine what exactly is claimed from what already had been practiced in the prior art or what remained to be determined in the future.

In *Halliburton*, for example, the patentee used the term "fragile gel" to distinguish the prior art. *Id.* at 1246. Even though these were terms that a layperson might understand, in the patent context they provided no concrete boundary between what was covered by the claims and what was not. The patentee provided no definition to delineate the broad and generic term. The Court therefore held that claims using the term "fragile gel" were indefinite. *Id.* at 1256.

Here, as in *Halliburton*, defining clear boundaries is particularly important because the "side effects" claim term was the one and only distinction Sepracor made over the prior art. Under Sepracor's open-ended proposed construction, there would be no defined boundary for the side effects that are included within the scope of the asserted claims. Barr's proposed construction, on the other hand, refers directly to the support found in the patent specification and provides a definite boundary for which side effects are included in the scope of the claims, namely central nervous system, cardiac, and teratogenic side effects. Applying the claim construction canon that one should preserve validity where possible, Barr's proposed construction should be used because Sepracor's proposal would render the claim invalid as indefinite. *Medtronic Navigation*, 222 F. App'x at 956.

B. Sepracor's Proposal Ignores The Written Description Requirement

"With regard to the written description test, this court has previously explained, 'the test for compliance with § 112 has always required sufficient information in the ***original disclosure*** to those that the inventor possessed the invention ***at the time of the original filing***.'" *Metabolite Labs., Inc. v. Laboratory Corp.*, 370 F.3d 1354, 1366 (Fed. Cir. 2004) (quoting *Moba v. Diamond Automation, Inc.*, 325 F.3d 1306, 1320 (Fed. Cir. 2003)) (emphasis added). In January 1990, when Sepracor filed its patent application, it represented that using R-albuterol reduced

"central nervous system," "cardiac," and "teratogenic" side effects. These were the side effects that Sepracor believed would be reduced by using R-albuterol. Sepracor cannot now expand the scope of the invention beyond what was actually described in its original January 1990 disclosure. *E.g.*, *LizardTech*, 424 F. 3d at 1346 (holding that the description of one method in the specification cannot support claims for "any and all means for achieving that objective").

New developments and disclosures made thereafter cannot be claimed. In *Schering Corp. v. Amgen, Inc.*, 18 F. Supp.2d 372, 377 (D. Del. 1998), this Court considered a patent relating to the synthesis of human alpha interferon ("IFN-alpha"). The patent originally referred to "leukocyte interferon," but six months later when a committee of scientists adopted new nomenclature to describe interferon, the inventor amended the claims to substitute "IFN-alpha" for "leukocyte interferon." *Id.* at 390. The Court found that the substitution imported scientific advances into the claims that simply were not present at the time the application was filed. On appeal, the Federal Circuit reached the same conclusion (although with slightly different reasoning), recognizing that "[t]o grant broader coverage would reward [the inventor] for inventions he did not make." *Schering Corp. v. Amgen, Inc.*, 222 F.3d 1347, 1354 (Fed. Cir. 2000).

The point of the specification is to define the patentee's invention ***at the time it filed the patent***, not later:

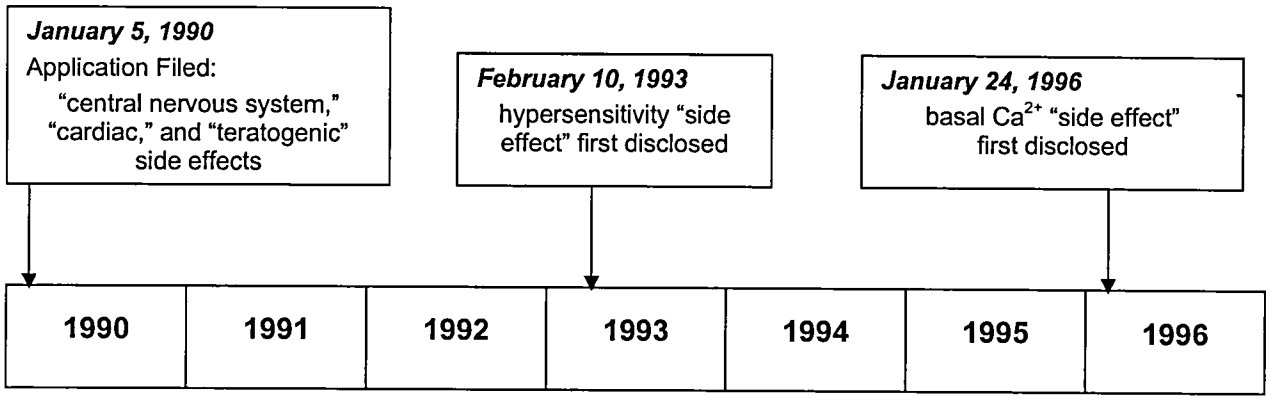
> [t]he written description requirement prevents applicants from using the amendment process to update their disclosures (claims or specifications) during their pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of invention.

Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255 (Fed. Cir. 2004). The issue here is what did Sepracor actually possess as a claimed invention in January 1990, when it submitted the

patent application. Sepracor noted in that patent application which side effects might be reduced by using R-albuterol, and listed central nervous system, cardiac, and teratogenic side effects. It cannot now extend the claims to cover other side effects that were first identified ***after*** the January 1990 filing date. *Phillips*, 415 F.3d at 1313 ("We have made clear, moreover, that the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question ***at the time of the invention, i.e. as of the effective filing date of the patent application.***") (emphasis added); *Schering*, 222 F.3d at 1353 ("In sum, this court must determine what the term meant ***at the time the patentee filed the [original] application.***") (emphasis added).

As it turned out, Sepracor could not prove that there was any reduction in the side effects listed in its original specification. When Sepracor tried to run tests to show tremor, one of the expressly-listed "central nervous system" side effects, it found that there were none, and said so to the Patent Office during prosecution. (Ex. 18, Sepracor's 11/20/97 Amendment, at 3.) Sepracor showed no other central nervous system, cardiac, or teratogenic effects. Instead, ***years after*** filing the January 1990 application, Sepracor did experimental work and relied upon new studies by others, resulting in new disclosures to the Patent Office incorporating newly acquired information not known at the time of the application. For example, on February 10, 1993, Sepracor disclosed to the Patent Office that "hypersensitivity" was another type of effect attributable to racemic albuterol. (Ex. 11, Sepracor's 2/10/93 Amendment, at 5-6.) On that date, Sepracor submitted an expert declaration, a new reference dated after January 1990, and a new argument referring to hypersensitivity, which Sepracor later described as the need for "ever-increasing doses of racemic albuterol." (*Id.*; Ex. 14, Sepracor's 12/7/93 Preliminary Remarks, at 3.) Hypersensitivity is not mentioned in the original patent specification. In fact, as part of its

February 10, 1993 submission, Sepracor admitted that hypersensitivity was a "previously undisclosed advantage." (Ex. 11, 2/10/93 Aberg Decl., at 6.) The same after-the-fact disclosure took place several more years later for "basal Ca^{2+} levels," an alleged effect that Sepracor first described in a submission made on January 24, 1996. (Ex. 16, Sepracor's 1/24/96 Interview Summary, at 2.) This timeline of disclosures shows what Sepracor disclosed to the Patent Office concerning side effects eliminated with the administration of R-albuterol:



At bottom, in January 1990, when Sepracor filed the first application eventually resulting in the patents in suit, it was aware of central nervous system, cardiac, and teratogenic side effects. These were therefore the only side effects Sepracor disclosed. As in the *Schering* case discussed above, other effects were indisputably identified years later and cannot now be claimed. "To grant broader coverage would reward [the patentee] for inventions he did not make." *Schering*, 222 F.3d at 1354. A similar analysis applied in *Medtronic Navigation*, where the patent specification did not describe all kinds of tracking systems, but only an "acoustic" tracking system, and the patentee could not therefore extend the scope of the claims beyond what was actually disclosed in the specification. *Medtronic Navigation*, 222 F. App'x at 956 ("A claim is to be construed in light of the written description that supports it.").

Sepracor here did not describe, and did not know about, potential side effects associated with the use of racemic albuterol other than central nervous system, cardiac, and teratogenic effects. Therefore, Sepracor should not now be allowed to expand the scope of its claims to other effects not contemplated when the specification was filed, and not described in the specification. Barr's proposed construction finds direct support in the patent specification as of the January 1990 date when Sepracor's first application was filed and is the appropriate construction of "side effects" for purposes of this case.

CONCLUSION

For all the above reasons, Barr respectfully requests that the Court construe "side effects" to mean "central nervous system effects (such as tremor, nervousness, shakiness, dizziness and increased appetite), cardiac effects (such as cardiac arrhythmia), and teratogenic effects."

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